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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,477	11/01/2000	Andre Cesar Baeck	CM1762M/VB	1249

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/24/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,477

Applicant(s)

BAECK ET AL.

Examiner

Manjunath N Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,15-21,24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,15-21,24 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1, 2, 15-21, 24, 26-28 are still at issue and are present for examination.

Applicants' arguments filed on 5-28-02, paper No. 7, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The use of the trademark PEG(NPC)2, t-BOC-NH-PEG-NH2 etc. on page 15 (1st, 2nd and 3rd paragraphs) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 is rejected because of the presence of trademark/trade names.

According to MPEP 2173.05(u), "while the presence of a trademark or trade name in a claim is not per se improper, the claim should be carefully analyzed to determine how the mark or name

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is used in the claim. It is also important to recognize that a trademark or a trade name is used to identify a source of goods and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name”.

In the above context, the trademark or trade names of the non-amino acid linker agents have been used in the claim as a limitation to identify or describe a particular material or product and hence the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular product or material. In fact, the value of a trademark would be lost to the extent that it became descriptive of the product rather than used as an identification of a source or origin of a product. Thus the use of trademark or trade name in the above claim to identify the linking agent renders the claim indefinite and also constitutes an improper use of the trademark or trade name.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 15-19, 26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulein et al. (WO 94/07998, 14 April, 1994). This rejection is based upon the public availability of a printed publication. Claims 1-2, 15-16, 26, 28 of the instant application are drawn to a fabric-softening protein hybrid comprising an amino acid sequence comprising a

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cellulose binding domain (CBD) linked to a fabric softening protein wherein said fabric softening protein is linked to said amino acid sequence comprising CBD, via an amino acid and/or non-amino acid linking region, wherein the CBD is selected from the group consisting of the CBD from *H.insolens*, wherein several amino acid sequences (2-10 or 2-50 amino acid sequences) comprising the CBD are cross linked via an amino acid and/or non-amino acid linking region, wherein the fabric care composition comprising the above hybrid protein comprises another fabric care ingredient and a method wherein the above fabric care composition is used to treat a fabric. Schulein et al. disclose such a hybrid protein comprising one or more amino acid sequences (two CBDs) comprising a cellulose binding domain, linked to a softening protein (cellulase) via an amino acid linker wherein the CBD is the CBD from *H.insolens*, wherein the fabric care composition comprising the above hybrid protein comprises another fabric care ingredient and a method wherein the above fabric care composition is used to treat a fabric. Therefore Schulein et al. anticipate claims 1-2, 15-19, 26, 28 of this application as written.

In response to the previous Office action, applicants have traversed the above rejection arguing and drawing the attention of the Examiner to the amended claims which obviate the above rejection. Applicants argue that Schulein et al. fails to disclose a fabric care composition comprising one or more amino acid sequence(s) comprising the fabric softening protein hybrid of claim 1 as now required by claim 2 and therefore the rejection should be withdrawn. Examiner respectfully disagrees. As explained above Schulein et al. do disclose a composition comprising the fabric softening protein hybrid of claim 1. Therefore the above rejection is maintained.

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Claims 1-2, 15-16, 21, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilkes et al. (WO 93/05226, 18 Mar 1993). This rejection is based upon the public availability of a printed publication. Claims 1-2, 15-16, 21, 28 of the instant application are drawn to a fabric softening protein hybrid comprising an amino acid sequence comprising a CBD linked to a fabric softening protein wherein said fabric softening protein is linked to said amino acid sequence comprising CBD, via an amino acid and/or non-amino acid linking region, wherein the CBD is the CBD from *C.fimi*, wherein said softening protein is an inactive enzyme and/or a C18 alkyl quaternary wheat protein derivative, and a method wherein the above fabric care composition is used to treat a fabric. Gilkes et al. disclose such a hybrid softening protein wherein the softening protein is an inactive cellulase enzyme linked to a CBD from *C.fimi* through an amino acid linker. The reference also teaches a method to treat a piece of a fabric with the above hybrid protein to impart certain specific properties to the fabric. Therefore, Gilkes et al. anticipate claims 1-2, 15-16, 21, 28 as written.

In response to the previous Office action, applicants have traversed the above rejection arguing and drawing the attention of the Examiner to the amended claims which obviate the above rejection. Applicants argue that Gilkes et al. fails to disclose a fabric care composition comprising amino acid sequence(s) comprising a cellulose binding domain linked to softening protein via an amino acid or non-amino acid linking region as now required by claim 1 and therefore the rejection should be withdrawn. Examiner respectfully disagrees. As explained above and contrary to applicant's argument Gilkes et al. do disclose a composition comprising

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the fabric softening protein hybrid of claim 1 wherein the CBD and the softening protein are linked through an amino acid linker. Therefore the above rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 15-21, 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulein et al. and Gilkes et al. as applied to claims 1-2, 15-19, 21, 26, 28 above, and further in view of Linder et al. (J. Biol. Chem., Vol. 271(35):21268-21272, 1996) and the high level of knowledge existing in the art of making detergent compositions. Claims 1-2, 15-21, 26-28 are drawn to a fabric softening protein hybrid or a fabric care composition comprising such a hybrid protein wherein the hybrid protein comprises a CBD linked through an amino acid linker to an active/inactive softening protein, specifically a hybrid protein comprising the amino acid sequence of the N-terminal CBD of *T.reesei* CBHII linked to C terminal CBD of *T.reesei* CBHI, wherein said composition comprises such a hybrid protein and a fabric care ingredient such as a cationic surfactant, a clay, additional enzyme such as a transferase and/or mixtures thereof and a method of using such a hybrid protein.

Schulein et al. provides a composition comprising a CBD obtained from *H.insolens* linked to a softening protein through an amino acid linker and Gilkes et al. teach methods of making a hybrid fabric softening protein by making use of at least two CBDs from *C.fimi* and a

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softening protein which is inactive or active (see pages 5 through 9). However, the references do not teach the use of a specific construction of double CBD obtained from *T.reesei* linked to a softening protein through an amino acid or non-amino acid linker region such as that described in claim 20 of the instant application.

Linder et al. teach the construction of a double CBD in which they fuse the N-terminal CBD of *T.reesei* CBHII to the c-terminal CBD of CBHI by a linker region of 24 amino acids. Linder et al. show that the double CBDs they constructed has a higher binding affinity than either of the two single domains by themselves.

The art of detergent composition teaches the use of cationic surfactants to increase the efficiency of the detergents as also the use of clay, other enzymes such as transferases and or mixtures thereof.

Armed with the teaching of Schulein et al., Gilkes et al. to construct hybrid proteins which efficiently polish cellulose fibers, and with the teachings of Linder et al. that a double CBD of *T.reesei* increases the affinity of the double domains to cellulose fibers along with other general information common in the art of detergent composition, it would have been obvious to one of ordinary skill in the art to develop a fabric care composition comprising a hybrid softening protein as described in the above claims. One of ordinary skill in the art would have been motivated to do so in order to improve the efficiency of the existing detergent compositions such that the fabric which is washed using such detergent composition appears more polished after the wash. One of ordinary skill in the art would have a reasonable expectation of success as Schulein et al. and Gilkes et al. provide a step by step method for construction of a hybrid protein, and Linder et al. provide the double CBD and the art provides sufficient information in

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formulating detergent compositions by addition of other components such as cationic surfactants, clay, transferases etc.

Therefore, the above claims would have been *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office action, applicants have traversed the above rejection arguing and drawing the attention of the Examiner to the amended claims which obviate the above rejection. Applicants argue that Schulein et al. in view of Gilkes et al. and in further view of Linder et. al. fails to teach or suggest a fabric care composition comprising one or more amino acid sequence(s) comprising the fabric softening protein hybrid of claim 1 wherein the CBD and the softening protein are linked through an amino acid or non-amino acid linker region as now required by claim 1 and therefore the rejection should be withdrawn. Examiner respectfully disagrees. As explained above Schulein et al., Gilkes et al. and Linder et al. taken together render the above invention *prima facie* obvious. Therefore the above rejection is maintained.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulein et al. or Gilkes et al. as applied to claim 1 above, and further in view of Zalipsky et al. (WO 94/21281, 9-29-1994) or Sigma catalogue, (1992, Cat No. M8779 or M7642) and the high level of knowledge existing in the art of protein-protein cross-linking.

Claim 24 is drawn to a fabric softening protein hybrid or a fabric care composition comprising such a hybrid protein wherein the hybrid protein comprises a CBD linked to

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softening protein via an amino acid and/or non-amino acid linking region, wherein said linking region is a polymer selected from a group of polymers.

Schulein et al. and Gilkes et al. references as it applies to claim 1 has already been discussed above. However, claim 24 is drawn to a hybrid protein in which a non-amino acid linker is used. Zalipsky et al. teach the use of PEG polymers to make hybrid proteins without amino acid linkages. Specifically, Zalipsky et al. teach the hybrid protein Biotin-PEG-Avidin complexes. The use of such agents to make a protein-protein link appears to be well known in the art. The Sigma Chemical Co. catalog also lists agents such as G-maleimidobutyric acid and Maleimidobutyric acid N-hydroxysucciniamide ester as useful for modifying thiol groups in proteins and also as hetero bi-functional reagent for protein conjugation. It is also common knowledge in the art that use of such agents including the PEG polymers stabilizes the protein hybrid.

Combining the references of Schulein et al. or Gilkes et al. with that of Zalipsky et al., or the information in the Sigma catalog and the common knowledge in the art regarding protein-protein conjugation, it would have been obvious to one of ordinary skill in the art to use non-amino acid linking agents instead of amino acid linkers to link the CBD with the softening protein. One of ordinary skill in the art would have been motivated to do so as the non-amino acid linkers would not be prone to protease action and thus stabilize the hybrid protein. Furthermore, use of non-amino acid linkers would allow one skilled in the art to cross-link as many CBDs to the hybrid protein as possible. One of ordinary skill in the art would have a reasonable expectation of success as Gilkes et al. or Schulein et al. show the use of amino acid

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linkers and Zalipsky et al. show the demonstrate the use of non-amino acid linkers. Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

In response to the above rejection, applicants may argue that Examiner has not provided a reference that specifically teaches the use of polymers claimed in claim 24. However, such an argument would not be persuasive to overcome the rejection because even though the reference does not teach specifically the polymers listed, the use of non-amino acid linkers was well known in the art and as applicants have themselves have indicated in their specification, large number of such reagents can be used and use of few specific ones is entirely one's choice. Applicants have also not indicated any specific advantage involved in using those specific polymers. Therefore irrespective of any specific polymers, the idea of using a non-amino acid reagent as a linking agent would have been *prima facie* obvious.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao. Ph.D.
July 23, 2002


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1600